

Electronic Cigarettes

Unregulated, Untested

Fact sheet for citizens and health care professionals by: Department of Public Health and Human Services Montana Tobacco Use Prevention Program

E-cigarettes have:

- substantial risk to the user; and
- no approval or regulation by the Food and Drug Administration (FDA).

MONTANA'S STATE
MEDICAL OFFICER

Steven D. Helgersen, M.D.
asks,

**“How does
this product fit
with the mission
of medicine?
It doesn't.**

**I see no benefit to it,
and I see the
possibility
of substantial
harm.”**

E-cigarettes, or electronic cigarettes, have been largely unregulated, and there have been many doctors and others questioning the safety of these products.

Electronic cigarettes typically use a rechargeable battery-operated heating element to vaporize the nicotine in a replaceable cartridge. Nicotine, the addictive element of tobacco, is usually dissolved in propylene glycol, a clear and colorless liquid that is commonly found in inhalers, cough medicines and other products. A laboratory analysis of e-cigarettes samples by FDA revealed that they contain carcinogens and toxic chemicals such as diethylene glycol, an ingredient used in antifreeze.¹

Dr. Helgersen, State Medical Officer, joins the U.S. Food and Drug Administration (FDA), American Lung Association, American Cancer Society, American Heart Association, Campaign for Tobacco-Free Kids, and other public health organizations in voicing concerns about these new drug delivery devices.¹ The FDA and other public health experts have issued warnings about their safety, which focus on several key issues.

According to the FDA, “e-Cigarettes may contain ingredients that are known to be toxic to humans, and may contain other ingredients that may not be safe. Additionally, these products may be attractive to young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.”¹

Because clinical studies about the safety and efficacy of these products have not been submitted to FDA, consumers currently have no way of knowing

- whether e-cigarettes are safe for their intended use,
- what types or concentrations of potentially harmful chemicals are found in these products, or
- how much nicotine they are inhaling when they use these products.²

(Continued)



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FDA did not appeal the decision by the U.S. Court of Appeals for the D.C. Circuit in *Sottera, Inc. v. Food & Drug Administration*, holding that e-cigarettes and other nicotine-containing products are not drugs or devices unless they are marketed for therapeutic purposes, but that other nicotine-containing products can be regulated as “tobacco products” under the Federal Food, Drug, and Cosmetic Act. Therefore, FDA intends to develop regulations for electronic cigarettes.³

FDA has approved and found safe many products for cessation, but these do not include e-cigarettes. For more information, please contact the Montana Quit Line, 1-800-QUIT NOW.

Report Adverse Events

Please report adverse events with e-cigarettes by filling out the online form at www.accessdata.fda.gov/scripts/medwatch/medwatchonline.htm or calling 1-800-FDA-1088.

Sources

1. FDA. *Consumer Updates: FDA Warns of Health Risks Posed by E-Cigarettes*. July 23, 2009; Available from: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>
2. FDA. *News Release: Concerns Voiced by the Public Health Experts About Electronic Cigarettes*, 7/22/09; Available from: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173175.htm>
3. FDA. *News & Events: Ecigarettes* 10/6/11. Available from: <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>
4. Lorillard acquires Blu Ecigs for \$135 Million. 4/25/12. Available from: [http://www.csnews.com/top-story-tobacco-lorillard_acquires_blu_ecigs_for_\\$135m-60981.html](http://www.csnews.com/top-story-tobacco-lorillard_acquires_blu_ecigs_for_$135m-60981.html)